Office of Research Integrity:
Scope and process of handling allegations of misconduct

John Dahlberg, Ph.D.
Director
Division of Investigative Oversight
Office of Research Integrity

ORI's Mission

Mission: To promote the integrity of PHS-supported extramural and intramural research programs

- Respond effectively to allegations of research misconduct

- Promote research integrity

Definition of Research Misconduct

- Fabrication is making up data or results and recording or reporting them
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit
- Research misconduct does not include honest error or differences of opinion

  (42 CFR Part 93.103)

Proof of Research Misconduct

Requires -

- That there be a significant departure from accepted practices of the relevant research community, and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence, (42 CFR Part 93.104)

Additional ORI Activities

- Administer the Assurance program, a database of all institutions eligible to receive PHS funds
- Correct or retract research publications to protect the integrity of the scientific literature
- Protect the confidentiality of respondents, complainants, and witnesses
- Protect witnesses from retaliation

  (42 CFR 93.300 (d))
- Exclude dishonest investigators from PHS and Federal agency funded research
- Make public findings of misconduct so that institutions and individuals will be aware of wrongdoing

ORI lacks jurisdictions for many types of inappropriate behavior: some are referred to other agencies

- Misuse of human or animal subjects
- Misconduct and other complaints involving FDA-regulated research
- Financial mismanagement
- Radiation or biosafety hazards
- Conflict of interest
- Honest error or honest differences in interpretations or judgments of data
- Authorship or credit disputes
- Duplicate publication
- Collaboration agreements or research-related disputes among collaborators
- Intellectual property

Research Misconduct in Clinical Research

- By policy, in clinical trails, certain types of falsifications are not handled by ORI as allegations of research misconduct. These include:
  - Falsified or forged consent forms
  - Failure to report an adverse event to the IRB or sponsor
  - Protocol deviations such as entering ineligible subjects, administering an off-protocol drug, forging a physician's signature on orders
  - Failure to obtain informed consent
  - Breach of patient confidentiality
  - Failure to obtain IRB approval for changes to protocol

Research Misconduct in Clinical Research, **(Continued)**

Behaviors that **<u>are</u>** considered research misconduct:

- Falsifications:
  - Substitutions of one subject's record for another's
  - Changing research record to favor the study's hypothesis
  - Altering eligibility dates and eligibility test results
  - Falsifying dates on patient screening logs
- Fabrications:
  - Not conducting interviews with subjects and creating records of the interview
  - Making up patient visits and inserting that record into the medical chart
  - Recording the results of follow-up visits with deceased subjects

Types of data that have been falsified or fabricated in clinical studies

- **Interviews**
- **Entry criteria**
- **Screening logs**
- **Approval forms**
- **Follow-up exams/data**
- **Consent forms**
- **Test scores**
- **Laboratory results**
- **Patient data**
- **Number of subjects**
- **Dates of procedures**
- **Protocol**
- **Study results**

ORI's Handling of Cases

- Allegation – at institution or at ORI
- Allegation Assessment – if at ORI, referred to institution
- Institution Inquiry
- Institution Investigation – institutional actions
- DIO Review of Institution's Investigation
- ORI Director's Decision on proposed administrative actions
- If misconduct, seek settlement or send charge letter followed by hearing
- If misconduct found, possible appeal
- With final departmental finding, impose administrative actions

A few differences between ORI and OHRP

- ORI makes findings against individuals, OHRP (generally) against institutions
- ORI's records are kept in a Privacy Act System of Records while OHRP's are publically available.
- ORI's compliance reviews against institutions are infrequent and result from inadequate investigations